

Facility Licensing and Investigations Section of the Department of Public Health

Approved
5/28/19
SHN

Provider ID No.: 070019	Building: 01-Entire Campus East & West	Survey Commenced on May 9, 2019
Name of Provider: <u>Milford Hospital</u>	Address: 300 Seaside Avenue Milford, CT 06460	
Violation of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut	Plan of Correction	Completion Date

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6), _

1. Based on medical record reviews, review of facility policy, review of facility documentation, and interview, for one of three patients' reviewed for surgical services (Patient #8), the facility failed to ensure the correct gamma implant was utilized during hip surgery. The finding includes:
 - a. Patient (P) #8 had open reduction internal fixation of the left hip on 11/12/18 by Medical Doctor (MD) #2 post fall. Review of the intraoperative implant record dated 11/12/18 identified that a left gamma nail was implanted, however, the immediate operative report labels for the implants identified, in part that a right gamma nail (instead of a left) was implanted during P #8's left hip surgery. P #8 was discharged on 11/17/18 to a long term care facility, fell and was readmitted to the facility on 11/19/18 with a left distal femur fracture. P #8 was transferred to Hospital #2 on 11/21/18 following stabilization due to the need for the assistance of a trauma surgeon during surgery. Facility documentation indicated that Hospital #2 reported to the facility that on 1/10/18, right sided gamma nail was removed from P #8's left femur during the left hip surgery that was conducted on 11/12/18. Interviews with MD #2, Surgical Technician (ST) #1 and Registered Nurse (RN) #1 on 5/7/19 at 10:27 AM, 11:16 AM and 8:30 AM respectively, noted that the case was difficult and although the Sales Representative read off the gamma implant details and opened the sterile implant, the implant box with the written details was not visualized by MD #2, ST#1 and/or RN #1. Further interview with MD #2 on 5/7/19 at 10:27 AM noted that although P #8 had the wrong side nail inserted during the surgery on 11/12/18, P #8's left femur accommodated the right gamma nail and this did not cause P #8's second fall/injury. Review of the facility Sales Representative policies dated 3/2013 and 6/2017 identified that under no circumstances may the Sales Representative participate in a procedure by handling, opening or dispensing sterile supplies and/or equipment. Subsequent to the event, the facility submitted a CAP (corrective action plan) to include policy revision requiring a second time out for implants, staff education and monitoring. The facility was found to be compliant with the CAP as submitted.

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<p>2. Based on medical record reviews, review of facility bylaws and interviews for one of three patients reviewed for infection (Patient #7), the facility failed to ensure diagnostic testing was completed when a wound infection was identified, to ensure proper treatment. The finding includes:</p> <p>a. Patient (P) #7 had perforated diverticulitis with peritonitis and had an exploratory laparotomy, abdominal washout and Hartmann Procedure with an end colostomy performed on 3/25/19 by Medical Doctor (MD) #6. The operative report dated 3/25/19 identified that the abdominal incision was closed, in part with staples. Postoperatively, P #7 received the IV (intravenous) antibiotics Zosyn and Flagyl until postoperative day #3 and oral Flagyl and Ciprofloxacin thereafter. An addendum progress note, by MD #6, dated 3/28/19 indicated there was erythema (redness) and purulence (containing pus) of the midline incision. The incision was opened and packed with Kerlex and a dry dressing. The medical record lacked documentation that a culture had been obtained of the new purulent incisional drainage. Interview with MD #6 on 5/9/19 noted that he did not obtain a culture of the midline incision on 3/28/19 because this was a superficial wound infection and the patient was on antibiotics that would cover gram negative bacteria and anaerobes. He further indicated the antibiotics would not cover MRSA (methicillin resistant staphylococcus aureus (gram positive bacteria). MD #6 further identified that P #7's wound healed well, however, after P #7 was discharged, P #7's Dermatologist performed a wound culture which resulted positive for MRSA and treated P #7 with Doxycycline. Interview with MD #5 (Infectious Disease) on 5/8/19 at 1:49 PM indicated that a MRSA infection could happen at any time from operation to wound closure. He further noted that treatment may be indicated if purulence is present and that a wound culture should be obtained to identify the bacteria and the infection should be treated with the narrowest antibiotic (as opposed to a broad spectrum antibiotic). Although the facility did not have a specific policy related to wound culturing, the rules and regulations of the medical staff identified that a member of the Organized Medical Staff (i.e. MD #6) shall be responsible for the timely and continuous medical care of each patient.</p>	See attachment #1	See attachment #1

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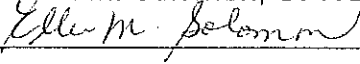
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- b. Review of a physician's order dated 8/3/17 at 11:16 AM directed to change the patient's JP dressing site as needed and daily with gauze packing. Review of the patient's clinical record for the period of 8/3/17 to 8/8/17 identified that the patient's JP drain site was monitored and the dressing was changed on 8/6/17 at 7:00 PM however the record failed to identify that the gauze packing was changed daily in accordance with the physician's orders. Review of Patient #5's electronic medical record and interview with the Nursing Director on 5/8/19 identified that the physicians' orders during the period of 8/3/17 to 8/4/17 were changed without discontinuing the previous orders and the treatment orders may not have been clear. The Director identified that this likely resulted in the patient's dressing changes being done PRN (as needed) at times, rather than daily and/or twice daily. The Director identified that, although there was no specific policy regarding the clarification of treatment orders, as a standard of practice when orders are not clear, nursing staff was expected to clarify the order with the prescribing physician. The Director identified that when this issue was identified in September 2017, a revised wound and ostomy policy was put into place to ensure that the wound/ostomy nurse consult is required.

Director's or Provider/Supplier Representative's Signature Ellen M. Solomon, CPHQ 	Title Interim Director, Quality Management	Date May 24, 2019
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DPH Violation #	Provider Plan of Correction	Completion Date
1.	<p>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6),</p> <p>Changes implemented to prevent a recurrence:</p> <ul style="list-style-type: none"> The Time Out Verification Policy (T-06-NRS-ORS) has been revised to demonstrate the need for the OR team to perform a second time out. Specifically, prior to implantation of any device, the OR team including the surgeon, will perform a second time out. This second time out will verify the implant is the correct one for the patient. The verification process includes: brand/manufacturer name, expiration date, name of implant, laterality, if appropriate, type of fixation and implant size. This will be documented in the surgical record. The Sales Representatives in the Operating Room Policy (S-15-NRS-ORS) has been revised to prohibit sales representatives from opening and dispensing sterile supplies/equipment (including implants/prosthetics) onto the sterile field. The Sales Representatives-Access to Hospital Policy (S-40-EXE) has been revised to prohibit sales representatives from opening and dispensing sterile supplies/equipment (including implants/prosthetics) onto the sterile field. OR nursing staff and credentialed medical staff were educated on the revised policies. Audits were performed on the newly implemented second time out process documentation. These audits were conducted on all surgical cases with implants for one month. Further audits will be conducted on 10 cases per month for 3 months. Policies revised as 01/2019. Education provided to OR staff on policy revisions 01/23/19 and 2/1/19. Education provided for surgical medical staff on policy revisions 2/7/19-2/15/19. <p>Monitoring plan:</p> <ul style="list-style-type: none"> Audits were performed on the newly implemented second time out process documentation. These audits were conducted on all surgical cases with implants for one month. Further audits were conducted on 10 cases per month for 3 months. <p>Responsible: Chair of Surgery Perioperative Nurse Manager</p>	<p>01/31/2019</p> <p>01/31/2019</p> <p>01/31/2019</p> <p>2/15/2019</p> <p>5/31/2019</p> <p>2/1/2019</p> <p>2/15/2019</p> <p>5/31/2019</p>

DPH Violation Letter May 17, 2019 / Dates of Visit May 6-9, 2019

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2.	<p>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (i) General (6).</p> <p>Changes implemented to prevent a recurrence:</p> <ul style="list-style-type: none"> The Chief Medical Officer will provide counseling with MD #6 on the rules and regulations of the Organized Medical Staff regarding the responsibility for the timely and continuous medical care of each patient. Counseling will include the findings of the violation. This violation will be presented at Med/Exec Committee by the chief medical officer. <p>Monitoring plan:</p> <ul style="list-style-type: none"> MD # 6 will be monitored for trends. <p>Responsible: Chief Medical Officer</p>	<p>5/31/2019</p> <p>5/28/2019</p> <p>Ongoing</p>
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4.	<p data-bbox="284 304 1177 409">The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1).</p> <p data-bbox="324 472 893 504">Changes implemented to prevent a recurrence.</p> <ul data-bbox="381 535 1185 798" style="list-style-type: none"> <li data-bbox="381 535 1185 682">• Milford Hospital clinical nursing staff have received High Reliability Organizational education which includes the communication technique stopping the line and requesting clarification of orders. <li data-bbox="381 682 1185 798">• Further education will be provided to medical/surgical nursing staff on the importance of assessing appropriate documentation of dressing changes against current orders. <p data-bbox="332 871 544 903">Monitoring plan:</p> <ul data-bbox="381 934 1161 1050" style="list-style-type: none"> <li data-bbox="381 934 1161 1050">• 5 or all charts for a period of two months will be reviewed to assess the documented dressing changes match the physician orders on the medical/ surgical floor <p data-bbox="332 1155 722 1186">Responsible: Director of Nursing</p>	<p data-bbox="1234 525 1364 556">5/31/2019</p> <p data-bbox="1242 661 1356 693">6/7/2019</p> <p data-bbox="1234 913 1364 945">7/31/2019</p>

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor
Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

May 17, 2019

Mr. Mark Toney President/CEO
Milford Hospital, Inc
300 Seaside Avenue
Milford, CT 06460

Dear Mr. Toney:

Unannounced visits were made to Milford Hospital, Inc on May 6, 7, 8, and 9, 2019 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations..

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by May 28, 2019.

The plan of correction shall include:

- (1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
- (2) the date each such corrective measure or change by the institution is effective;
- (3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
- (4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard.. If the violations are not responded to by May 28, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.



Phone: (860) 509-7400 • Fax: (860) 509-7543
Telecommunications Relay Service 7-1-1
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer



DATE(S) OF VISIT: May 6, 7, 8, and 9, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

An telephone conference has been scheduled for June 6, 2019 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,



Susan H. Newton, RN, SNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:bh:

Complaint #CT22818, CT22104, CT21967, CT24370, CT24082, CT24010, CT23009, CT25341, CT24788, CT22827

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The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1).

4. Based on clinical record review, interview and review of facility policy for one of three patients with wounds (Patient #5) the facility failed to ensure that treatments were administered in accordance with physician's orders. The finding included:
 - a. Patient #5 was admitted to the hospital on 7/27/17 with diagnoses that included acute diverticulitis. Review of a computerized tomography (CT) scan report dated 7/27/17 identified a peri-sigmoidal abscess and intravenous (IV) antibiotics were initiated. On 7/28/17 the patient underwent an insertion of a percutaneous pelvic abscess drain. Review of the patient's clinical record for the period of 7/28/17 to 7/31/17 identified the patient demonstrated clinical improvement with a reduced white blood cell count however review of a nurse's note dated 8/1/17 identified that the patient had increased abdominal cramping with nausea. Review of an abdominal and pelvic CT scan report dated 8/1/17 identified that patient had a new abscess and severe active diverticulitis. Surgery was scheduled for 8/2/17. Review of the patient's operative report dated 8/2/17 identified that the patient underwent a Hartmann Procedure and a sigmoid colectomy with end colostomy. The report identified that a Jackson-Pratt (JP) drain was placed in the patient's right lower abdomen. The patient's midline surgical incision was packed and a sterile dressing was placed over the incision. Review of a physician's order dated 8/3/17 directed, in part, the midline dressing was to be changed daily and as needed with Iodoform or gauze. A physician's order dated 8/4/17 at 9:46 AM directed to pack two openings in the midline incision with moist to dry gauze twice daily and to change the drain sponge as needed however, the clinical record failed to identify that the previous order had been discontinued. Review of the skin

DATE(S) OF VISIT: May 6, 7, 8, and 9, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

assessment records for the period of 8/5/17 at 9:00 AM to 8/6/17 at 11:00 PM identified that the patient's dressing was dry and intact, however the medical record failed to identify the dressing was changed twice daily as ordered. Review of a nurse's note dated 8/8/17 at 11:56 AM identified that the patient's abdominal dressing was changed. A review of the patient's clinical record for the period of 8/8/17 at 1:00 PM to 8/9/17 at 9:00 AM identified that the patient's dressing was dry and intact however, the note failed to identify that the dressing had been changed twice daily, as ordered.

- b. Review of a physician's order dated 8/3/17 at 11:16 AM directed to change the patient's JP dressing site as needed and daily with gauze packing. Review of the patient's clinical record for the period of 8/3/17 to 8/8/17 identified that the patient's JP drain site was monitored and the dressing was changed on 8/6/17 at 7:00 PM however the record failed to identify that the gauze packing was changed daily in accordance with the physician's orders. Review of Patient #5's electronic medical record and interview with the Nursing Director on 5/8/19 identified that the physicians' orders during the period of 8/3/17 to 8/4/17 were changed without discontinuing the previous orders and the treatment orders may not have been clear. The Director identified that this likely resulted in the patient's dressing changes being done PRN (as needed) at times, rather than daily and/or twice daily. The Director identified that, although there was no specific policy regarding the clarification of treatment orders, as a standard of practice when orders are not clear, nursing staff was expected to clarify the order with the prescribing physician. The Director identified that when this issue was identified in September 2017, a revised wound and ostomy policy was put into place to ensure that the wound/ostomy nurse consult is required.